K120584

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

JUL 10 2012

Wealth On (Jiangsu) Co., Ltd
Dongyuan Village, Hengji Town, Jianhu County
Yancheng, Jiangsu Province, China
Tel: 86- 21-33517339
Submitter's FDA Registration Number: 3009307502

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
5 Carey Street
Pennington, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: Feb 12, 2012

Device Name:	
Proprietary Name:	Powder Free Light-Yellow Stretch Vinyl Patient Examination Gloves (or other clients private labeling)
Common Name:	Patient examination glove
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel: General	Hospital
Product Code:	LYZ

Predicate Device Information:
(1) K110219, "Powder Free Vinyl Patient Examination Gloves", manufactured by "Wealth On (Jiangsu) Co., Ltd" (our own company)

Device description:

Powder free light-yellow stretch vinyl patient examination gloves are made of polyvinyl chloride, and are non sterile that meets all of the requirements of ASTM standard D 5250-06, except for sterility requirements. They have light yellow color.

Intended Use:
The powder free light-yellow stretch vinyl patient examination glove, is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. It has light yellow color and is sold as non sterile.

Comparison to Predicate Devices
The powder free light-yellow stretch vinyl patient examination gloves, non sterile are compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K110219, "Powder Free Vinyl Patient Examination Gloves", manufactured by "Wealth On (Jiangsu) Co., Ltd" (our own company)

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device (K110219)
Indication for Use	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Same
Basic Design	A garment covering the hand and wrist area. Gloves have separate sheaths or openings for each finger and the thumb.	Same
Materials	Poly Vinyl Chloride	Same
Size	XS, S, M, L, XL	Same
Single Use	Yes	Yes
Color	Light Yellow	Colorless
Sterile	Non sterile	Non sterile

The only difference is that the predicate device is colorless and does not contain any pigment. The new device contains white and yellow pigments and color is light yellow. The MSDS of the pigments are in Appendix 2 and they are both non-hazardous materials. The gloves made using these pigments have shown to not causing irritation and sensitization effects (Section 15: Biocompatibility).

The following table shows similarities and differences of the performance between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in the respective consensus standards, and results for Powder Free Light-Yellow Stretch Vinyl Patient Examination Gloves (or other clients private labeling), manufactured by *"Wealth On (Jiangsu) Gloves Co., Ltd"* met all relevant requirements in the test standards, and are comparable to the predicate device.

Table 5.2: Comparison of Physical, Biocompatibility and Performance Testing

Description	Our Device	Predicate Device (K110219)
Dimension	Meets ASTM D5250-06	Meets ASTM D5250-06
Physical Property	Meets ASTM D5250-06	Meets ASTM D5250-06
Free of Pinhole	Meets ASTM D5151-06	Meets ASTM D5151-06
Residue Powder	Meets ASTM D6124-06	Meets ASTM D6124-06
Primary Skin Irritation (ISO 10993-10)	Passes	Passes
Dermal sensitization (ISO 10993-10)	Passes	Passes

More details of non-clinical tests are summarized in *Sections 15 & 18.*

A brief discussion of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its user-defined acceptance criteria and intended uses:

Powder free light-yellow stretch vinyl patient examination gloves meet requirements per ASTM D5250-06, ASTM D6124-06, ASTM D 5151-06, and ISO 10993-10. It is safe and effective, and its performance meets the requirements of its pre-defined acceptance criteria and intended uses.

A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

Substantial Equivalent Conclusions

Based on the comparison of intended use, design, materials, and performance, our powder free light-yellow stretch vinyl examination gloves are substantial equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wealth On Jiangsu Company, Limited
C/O Mr. Charles Shen
Manton Business and Technology Services
5 Carey Street
Pennington, New Jersey 08534

JUL 10 2012

Re: K120584
Trade/Device Name: Powder Free Light-Yellow Stretch Vinyl Patient Examination Gloves (or other clients Private Labeling)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: May 31, 2012
Received: May 31, 2012

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

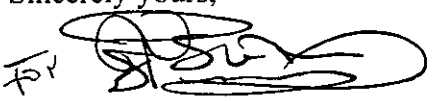
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number (if known): N/A K120584

Device Name: Powder Free Light-Yellow Stretch Vinyl Patient Examination Gloves (or other clients private labeling)

Indications for Use:

The powder free light yellow stretch vinyl patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. It has light yellow color and is sold as non sterile.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie - Williams

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120584